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Filed: January 28, 2000

B2

32. (Amended) An apparatus according to claim 27 or 28 further comprising a computer.

In the Specification

Please replace the paragraph beginning at page 5, line 6, with the following rewritten paragraph:

– This application claims benefit of U.S. Provisional Application 60/118,377 filed January 28, 1999, which is expressly incorporated herein by reference. –

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In the Drawings

Please replace Figures 1, 3 and 4, as filed with the enclosed amended drawings.

REMARKS

Claims 27-32 are pending. Claims 27-30 and 32 have been amended. Support for the amendment of Claim 27 is found on page 14, lines 18-22. Support for the amendment of Claim 28 is found in Claim 27 as filed and on page 14, lines 18-25. Support for the amendment of claims 29, 30 and 32 is found in the claims as filed. Amended drawings (Figures 1, 3 and 4) are submitted herewith. Support for the amendment is found in the specification at page 3, line 35 and page 4, lines 1-17, as filed. Also, Applicants note that the amendments already have been approved (see Response to Office Action of April 9, 2002, paragraph 2 (paper 14)).

A clean set of the pending claims appears above. Consideration of the amended claims, as well as the remarks that follow as they pertain to the claims, is respectfully requested.

Attached hereto is Appendix A entitled "Version with Markings to Show Changes Made" which depicts the changes made to the present application by the current amendment. Also enclosed is Appendix B that includes a clean version of the currently pending claims.

Claims 27 and 28 stand rejected under 35 U.S.C. §102(b) as being anticipated by

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Wells et al. (US 5,707,331); Claims 27, 28 and 30-32 stand rejected under 35 U.S.C. §102(b) as being anticipated by American Hospital Supply (GB 1 241 531); Claims 27 and 30-32 stand rejected under 35 U.S.C. §102(b) as being anticipated by Shigeru (JP 61-139756); and Claim 29 stands rejected under 35 U.S.C. §103(a) as being obvious over Tamai (JP 64-83153) in view of Wells et al., American Hospital Supply, or Shigeru.

Response to Detailed Action

Priority

Applicants acknowledge the Examiner's remarks regarding the present application's claim of priority. The specification has been amended to claim benefit from provisional application USSN 60/118,377, rather than claiming that the current application is a continuation of provisional application USSN 60/118,377. This should provide a proper claim of priority under 35 USC 119(e). Applicants appreciate the Examiner's attention to this matter.

Drawings

The Examiner indicated that a proper drawing correction or corrected drawings are required. In response, Applicants are submitting amended drawings to replace the drawings as filed. The drawings have been amended as requested.

Rejections Under 35 U.S.C. §102(b)

CLAIMS 27 AND 28

The Examiner rejects Claims 27 and 28 under 35 U.S.C. §102(b) as being anticipated by Wells et al. (5,707,331). More particularly, the Examiner argues that the reference of Wells et al. discloses a centrifuge with a rotor which is designed to hold reaction vessels at a tilt away from the axis of rotation. The Examiner further states that the device includes a waste reservoir and a tube. Applicants respectfully traverse.

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Wells et al. disclose a centrifuge which utilizes two-chambered containers, and is capable of locking and spinning these two-chambered containers in two separate positions: upright, *Wells et al.*, Fig. 4e and column 5 lines 52-61, and tilted toward the axis of revolution, *Wells et al.*, Figs. 4a-4d and 4f and column 5 lines 15-65. Wells et al. further provide methods for decanting liquids back and forth between the two chambers of the container using either gravity or centripetal force.

In contrast the present invention provides a centrifuge with a rotor to hold reaction vessels at a tilt away from the axis of rotation. *See Claim 27.* The apparatus also provides for a waste reservoir designed to hold the liquids that are expelled from the reaction vessels. This reservoir is either connected to the bottom of the centrifuge, *see Claim 27*, or connected to the centrifuge by a tube, *see Claim 28.*

An anticipation rejection requires that a single reference expressly or inherently disclose each and every element of a claim. *In re Paulsen*, 31 USPQ2d 1671, 1672 (Fed. Cir. 1994); MPEP §2131 (citing *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Additionally, the reference must enable and describe the claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *Id.* at 1673. To be enabling, the reference must teach the skilled artisan to make and use the full scope of the claimed invention without undo experimentation. *See Genentech Inc. v. Novo Nordisk A.S.*, 42 USPQ2d 1001, 1004 (Fed Cir. 1997).

Applicants submit that Wells et al. disclose neither the elements of a rotor designed to hold reaction vessels at a tilt away from the axis of rotation nor the element of a waste reservoir connected to the centrifuge, whether connected at the bottom of the centrifuge (Claim 27) or connected to the centrifuge by a tube (Claim 28). While Wells et al. do show in Fig. 3a that a vessel may adopt a position in which it tilts away from the axis of rotation, the apparatus that Wells et al. disclose do not hold the vessels in a tilt away from the axis of rotation. Wells et al. discloses that the container may be locked in the upright position in the following way: the

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locking plate (36) is locks the container in an upright position by engagement with protuberance (42). *Wells et al.*, Figure 3a and Column 5, lines 55-58. As one can see in Fig. 3a, while the container is shown in an orientation tilting away from the axis of rotation, the locking plate (36) is not engaged with the protuberance (42). If the locking plate was engaged with the protuberance, the vessel would be held in an upright position, parallel to the axis of rotation. The resulting position that the vessel adopts in use is more clearly shown in Fig. 4e, where the vessel is upright, and supernatant (46) has flowed from chamber 6 to chamber 8 under the influence of centripetal force. *Wells et al.*, Figure 4e and Column 5, lines 52-65. Nothing in *Wells et al.* teaches or suggests a centrifuge with a rotor to hold reaction vessels at a tilt away from the axis of rotation. Rather, and in distinct contrast to the claimed invention, *Wells* teaches that the reaction tubes may be held in one of two positions: either tilted inward, toward the axis of rotation, or held upright, parallel to the axis of rotation.

Further, while the Examiner states that *Wells* discloses a waste reservoir (6) and a tube (7), applicants submit that *Wells* does not in fact disclose a waste reservoir that is either connected to the bottom of the centrifuge, as required by Claim 27 as amended, or connected to the centrifuge via a tube, as required by Claim 28 as amended. First, while chamber (6) could certainly be viewed as a reservoir, it is most certainly not a waste reservoir. Webster's Third New International Dictionary defines waste (adjective) as: "thrown away or aside as worthless, defective or of no further use during or at the end of a process: refuse." Webster's Third New International Dictionary, 2580 (Merriam-Webster Inc. 1981). However, *Wells* uses chamber 6 as an initial repository for blood to be tested. See *Wells* column 5, lines 17-24. Since this blood is the starting material for the reactions to be performed, it is not waste, and thus the container holding it is not a waste reservoir. However, assuming *arguendo* that chamber 6 is a waste reservoir, *Wells* still fails to disclose each and every element of Claims 27 and 28, since chamber 6 is neither connected to the bottom of the centrifuge nor connected to the centrifuge via a tube. While chamber 6 is certainly connected to chamber 8 via tube 7, it is not connected to the centrifuge via this tube, only to the reaction vessel 8, and vessel 8 is not the centrifuge itself.

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Because Wells does not disclose each and every element of either Claim 27 or 28, Wells et al. does not anticipate Claims 27 and 28. Accordingly, Applicants respectfully submit that Claims 27 and 28 are patentably distinct from Wells et al.. Applicants respectfully request the withdrawal of the rejection of Claims 27 and 28 under 35 U.S.C. §102(b) as being anticipated by Wells et al.

CLAIMS 27, 28 AND 30-32

The Examiner rejects Claims 27, 28 and 30-32 under 35 U.S.C. §102(b) as being anticipated by American Hospital Supply (GB 1 241 539). More specifically, the Examiner argues that the reference of American Hospital Supply discloses a centrifuge device including a rotor which holds reaction vessels in a tilted position away from the axis of rotation. The Examiner further states that American Hospital Supply discloses a waste reservoir connected to the centrifuge by a tube, a liquid distribution system and a computer control. Applicants respectfully traverse.

American Hospital Supply discloses a centrifuge for washing and treating blood cells. The invention calls for washing fluids to be forcefully introduced into each tube at the open end thereof as such tube is traveling rapidly about an axis of centrifugation. *American Hospital Supply*, page 1, line 55-59. During this washing step, the reaction tubes are held in a position angled towards the axis of rotation. *American Hospital Supply*, Figures 3, and 6-8. American hospital supply also discloses that liquid may be decanted from the compacted washed cells by holding the tubes in an upright position during rotation, allowing the liquid to escape from the tubes under the influence of centripetal force. *American Hospital Supply*, Figure 9 and page 4, lines 32-35.

In contrast the present invention provides a centrifuge with a rotor to hold reaction vessels at a tilt away from the axis of rotation. *See Claim 27*. The apparatus also provides for a waste reservoir, which is connected to the centrifuge, designed to hold the liquids that are expelled from the reaction vessels. *Id.*

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As described above, an anticipation rejection requires that a single reference expressly or inherently disclose each and every element of a claim. *In re Paulsen*, 31 USPQ2d 1671, 1672 (Fed. Cir. 1994); MPEP §2131 (citing *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

Although the Examiner is correct in noting that the reference of American Hospital Supply discloses a computer controlled centrifuge device, which includes a rotor, and where the vessels are communicated with a waste reservoir, nothing in American Hospital Supply teaches or suggests a centrifuge with a rotor to hold reaction vessels at a tilt away from the axis of rotation. Rather, and in distinct contrast to the claimed invention, American Hospital Supply teaches that the reaction tubes either tilt inward, toward the axis of rotation or are held upright, parallel to the axis of rotation. *American Hospital Supply*, Figures 3 and 6-9,

Because American Hospital Supply does not disclose each and every element of Claims 27, 28 or 30-32, American Hospital Supply does not anticipate Claims 27, 28, and 30-32. Accordingly, Applicants respectfully submit that Claims 27, 28, and 30-32 are patentably distinct from American Hospital Supply. Applicants respectfully request the withdrawal of the rejection of Claims 27, 28, and 30-32 under 35 U.S.C. §102(b) as being anticipated by American Hospital Supply.

CLAIMS 27 AND 30-32

The Examiner rejects Claims 27 and 30-32 under 35 U.S.C. §102(b) as being anticipated by Shigeru (JP 61-139756). More specifically, the Examiner states that Shigeru discloses a centrifuge device, having a rotor which holds reaction vessels in a tilted position away from the axis of rotation, that there reaction vessels are communicated with a waste reservoir, and that the centrifuge includes a liquid distribution system and is computer controlled. Applicants respectfully traverse.

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Shigeru was written in Japanese, and an English translation of the patent will be supplied in a supplemental information disclosure statement. Shigeru discloses a centrifuge to automatically perform distribution, stirring, incubation and decantation. *Shigeru*, abstract (English translation). Shigeru further discloses a rotor capable of operating at multiple speeds, and holding tubes in multiple orientations. *Shigeru*, abstract and Figure 3. Shigeru further discloses an incorporated liquid distribution system, and a drain to collect expelled liquids. *Id.*

In contrast the present invention, as amended, provides a centrifuge with a rotor to hold reaction vessels at a tilt away from the axis of rotation. *See* Claim 27. The apparatus also provides for a waste reservoir, which is connected to the bottom of the centrifuge, designed to hold the liquids that are expelled from the reaction vessels. *See* Claim 27.

As noted previously, an anticipation rejection requires that a single reference expressly or inherently disclose each and every element of a claim. *In re Paulsen*, 31 USPQ2d 1671, 1672 (Fed. Cir. 1994); MPEP §2131 (citing *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

Applicants submit that Shigeru did not anticipate Claims 27 and 30-32 before the changes made under the present amendment. However, whatever the status of these Claims prior to the present amendments, Claim 27 as amended has the limitation that the reservoir is connected to the bottom of the centrifuge apparatus. *See* Claim 27. Shigeru does not either teach or suggest any such reservoir connected to the bottom of the centrifuge. Rather, Shigeru teaches that the reservoir is connected to drain 14, which in turn is located around the edge of the centrifuge, near the top of the apparatus. *Shigeru*, Figure 3 and translation page 293.

Therefore, Shigeru does not anticipate claims 27 and 30-32. Accordingly, Applicants respectfully submit that Claims 27 and 30-32 are patentably distinct from Shigeru. Applicants respectfully request the withdrawal of the rejection of Claims 27 and 30-32 under 35 U.S.C.

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§102(b) as being anticipated by Shigeru.

Rejection of Claim 29 Under 35 U.S.C. §103(a)

The Examiner rejects Claim 29 under 35 U.S.C. 103(a) as being unpatentable over Tamai in view of either Wells et al. or American Hospital Supply or Shigeru. More specifically, the Examiner states that Tamai discloses a centrifuge device with a rotor, which holds multiple microplate vessels and includes a waste reservoir. The Examiner further states that the only element missing from Tamai is holding the plates in a position away from the axis of rotation, an element which is provided by either Wells et al. or American Hospital Supply or Shigeru.

The Wells et al., American Hospital Supply and Shigeru references have been adequately discussed above.

Tamai was written in Japanese, and only the abstract has been translated into English. Referring to the abstract and Figures 1 and 2, Applicants note that Tamai discloses a rotor which holds multiple microplates and has a channel for collecting waste when in use. The apparatus in Tamai is designed to allow for automation of an entire analytical process, so that the analyst does not have to handle potentially contaminated equipment, thereby reducing the risk of contagion. In operation, the apparatus of Tamai appears to operate as follows: as the rotor rotates, a cleansing solution is sprayed across the surface of the rotor and across the microplates. *Tamai*, abstract. The cleansing liquid and contents of the microplate wells are expelled from the reaction wells and travel to the waste channel under the influence of the centrifugal force caused by the rotation of the rotor. *Id.* Applicants note that the rotor holds the microplates in an orientation such that the wells are parallel to the axis of rotation, not away from it.

In contrast the present invention provides a centrifuge with a rotor to hold reaction vessels at a tilt away from the axis of rotation. *See* Claim 27. The apparatus also provides for a

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waste reservoir designed to hold the liquids that are expelled from the reaction vessels. This reservoir is either connected to the bottom of the centrifuge, *Id.*, or connected to the centrifuge by a tube, *See* Claim 28. Additionally, the rotor is designed to hold microtiter plates. *See* Claim 29.

When rejecting claims under 35 U.S.C. §103(a), the Examiner must establish a *prima facie* case of obviousness. *See, e.g.* *In re Bell*, 26 USPQ2d 1529 (Fed. Cir. 1993); MPEP §2142. A *prima facie* case requires 1) that the prior art must provide one of ordinary skill with a suggestion or motivation to modify or combine the teachings of the references relied upon by the Examiner to arrive at the claimed invention; 2) the prior art must provide one of ordinary skill with a reasonable expectation of success; and 3) the prior art, either alone or in combination, must teach or suggest each and every limitation of the rejected claims. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP §706.02(j).

The Examiner's basic position is that it would have been obvious for one of ordinary skill in the art to combine the microplate, rotor and waste reservoir of Tamai with the outward tilt, away from the axis of rotation, of Wells et al., or American Hospital Supply or Shigeru. Applicants respectfully traverse the rejection. Applicants submit that the prior art references, taken alone or in combination, do not teach or suggest the present invention.

To this end Applicants submit that the Examiner has failed to point to any motivation for the combination of the references. While the Examiner suggests that it would have been obvious to combine the references, he has pointed to no teaching in the prior art that would have motivated the skilled artisan to do so. The Examiner suggests that the skilled artisan would have made the combination for the known and expected result of emptying the wells. However, Applicants note that Tamai has already achieved the result of emptying the wells by centrifugal action, and thus no modification of Tamai would be necessary to achieve the desired result of emptying the wells. If no modification is necessary to achieve a given result, it follows that there would be no motivation for such a modification, since the desired result has already

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been achieved. C.f. Winner International Royalty Corp. v. Wang, 53 USPQ 2d 1580, 1587 (district court found that there was no motivation to combine references because the invention disclosed in the prior art worked adequately, and thus there was no “problem” perceived).

Moreover, even assuming, *arguendo*, that there was motivation, Applicants submit that the references when combined fail to teach all of the claim elements. As discussed above, the reference of Wells et al. fails to teach the element of holding the reaction vessels away from the axis of rotation. Rather, Wells et al. teaches holding the reaction vessels either toward the axis of rotation, *see Wells et al. Fig. 3b*, or upright, *see id. Fig. 4e*. Further, Wells et al. fails to teach the element of a waste reservoir, whether connected either to the bottom of the centrifuge, as required by claim 27, or connected to the centrifuge by a tube, as required by Claim 28. Since Tamai teaches holding the microplates in an orientation such that the wells therein are upright, *see Tamai Figure 2*, and further teaches the use of a waste channel located around the edge of the rotor, neither of these references teaches either the element of holding the reaction vessels at a tilt away from the axis of rotation or the element of a waste reservoir connected either to the bottom of the centrifuge (Claim 27) or connected to the centrifuge via a tube (Claim 28).

As discussed above, the reference of American Hospital Supply fails to teach the element of holding the reaction vessels away from the axis of rotation. Rather, American Hospital Supply teaches holding the reaction vessels either toward the axis of rotation, *see American Hospital Supply Figs. 3 and 6-8*, or upright, *see id. Fig. 9*. Since Tamai teaches holding the microplates in an orientation such that the wells therein are upright, *see Tamai Figure 2*, none of these references teach the element of holding the reaction vessels at a tilt away from the axis of rotation.

As discussed above, the reference of Shigeru fails to teach the element of a reservoir attached to the bottom of the centrifuge. Rather, Shigeru teaches a reservoir connected to a drain that exists around the circumference of the centrifuge apparatus close to the top of the apparatus. *See Shigeru, Figure 3*. Likewise, Tamai teaches a discharge channel, which

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encircles the circumference of the rotor, and is at the top of the "centrifuge." Thus, neither Tamai nor Shigeru teaches the element of a waste reservoir connected to the bottom of the centrifuge.

For the reasons cited above, the Examiner has failed to establish a *prima facie* conclusion of obviousness against Claim 29. In particular, Tamai does not combine with any one of Wells et al., or American Hospital Supply, or Shigeru to provide all of the elements of the present invention. Additionally, one of skill in the art would not have been motivated to combine the cited references. Thus, Applicants respectfully submit that a *prima facie case* of obviousness has not been made and thus the rejection is improper. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. 103(a) be withdrawn.

CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and an early notification of such is solicited. If, upon review, the Examiner feels there are additional outstanding issues, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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APPENDIX A: Version with Markings to Show Changes Made

In the Claims

27. An apparatus comprising:

- a) a centrifuge comprising a rotor designed to hold reaction vessels at a tilt away from the axis of rotation; and
- b) a waste reservoir connected to the bottom of said centrifuge to hold liquids expelled from said reaction vessels.

28. An apparatus ~~according to claim 27 wherein said comprising:~~

- a) a centrifuge comprising a rotor designed to hold reaction vessels at a tilt away from the axis of rotation; and
- b) a waste reservoir is connected with a tube to said centrifuge with a tube to hold liquids expelled from said reaction vessels.

29. (Amended) An apparatus according to claim 27 or 28 wherein said rotor comprises a plurality of holders, each holder designed to hold at least one microtiter plate.

30. (Amended) An apparatus according to claim 27 or 28 further comprising a liquid distribution system.

32. (Amended) An apparatus according to claim 27 or 28 further comprising a computer.

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APPENDIX B: Pending Claims

27. An apparatus comprising:

- a) a centrifuge comprising a rotor designed to hold reaction vessels at a tilt away from the axis of rotation; and
- b) a waste reservoir connected to the bottom of said centrifuge to hold liquids expelled from said reaction vessels.

28. An apparatus comprising:

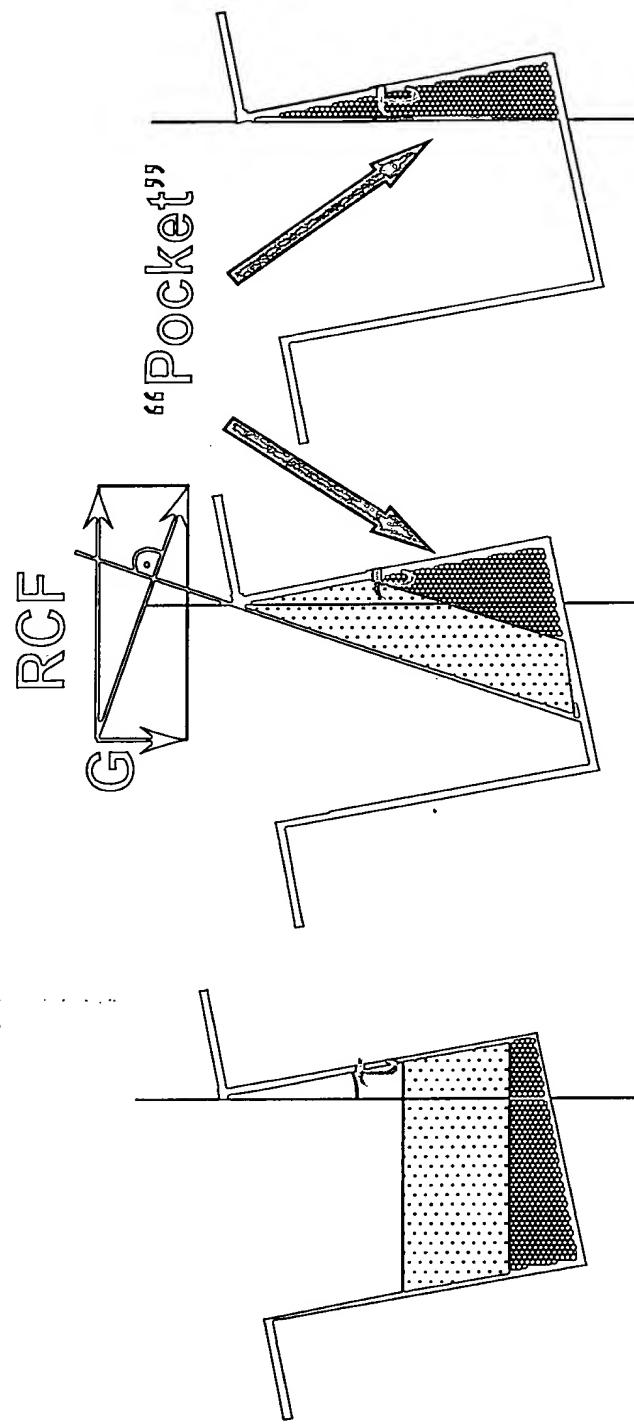
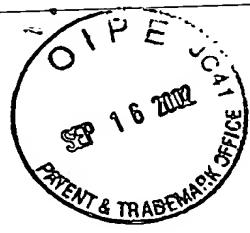
- a) a centrifuge comprising a rotor designed to hold reaction vessels at a tilt away from the axis of rotation; and
- b) a waste reservoir connected with a tube to said centrifuge to hold liquids expelled from said reaction vessels.

29. An apparatus according to claim 27 or 28 wherein said rotor comprises a plurality of holders, each holder designed to hold at least one microtiter plate.

30. An apparatus according to claim 27 or 28 further comprising a liquid distribution system.

31. An apparatus according to claim 30 wherein said liquid distribution system is integrated into the centrifuge.

32. An apparatus according to claim 27 or 28 further comprising a computer.



High speed

Fig. 1C

Low speed

Fig. 1B

No rotation

Fig. 1A

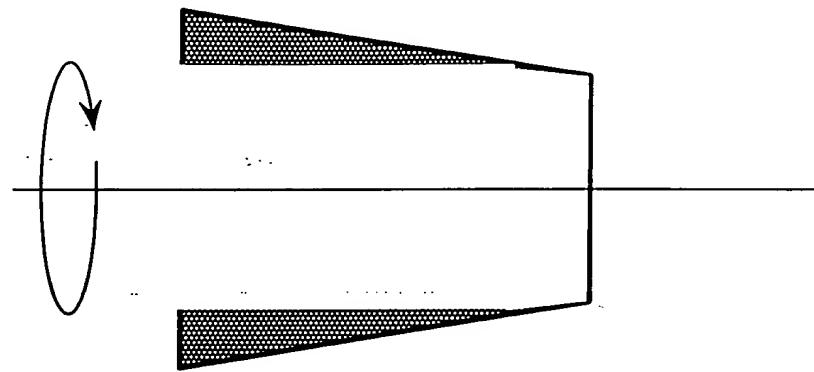
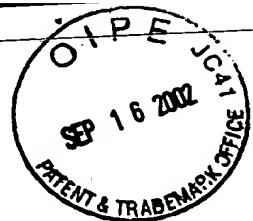


FIG. 3B

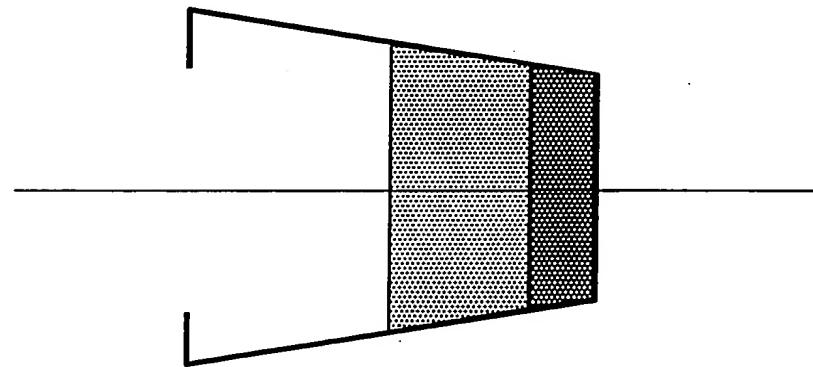


FIG. 3A

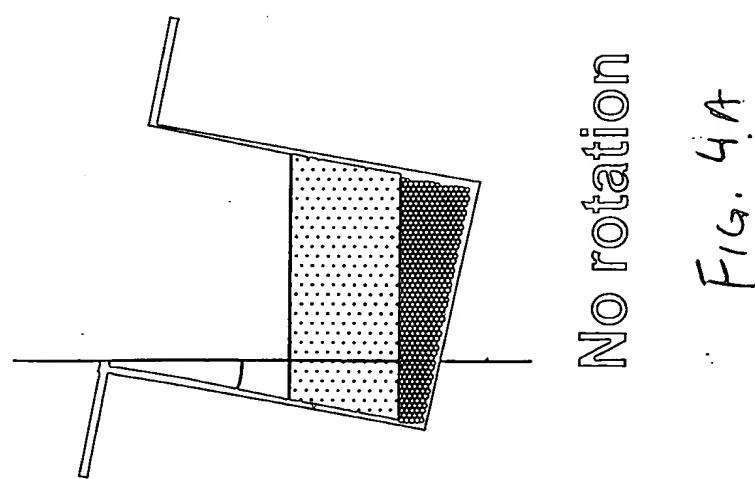
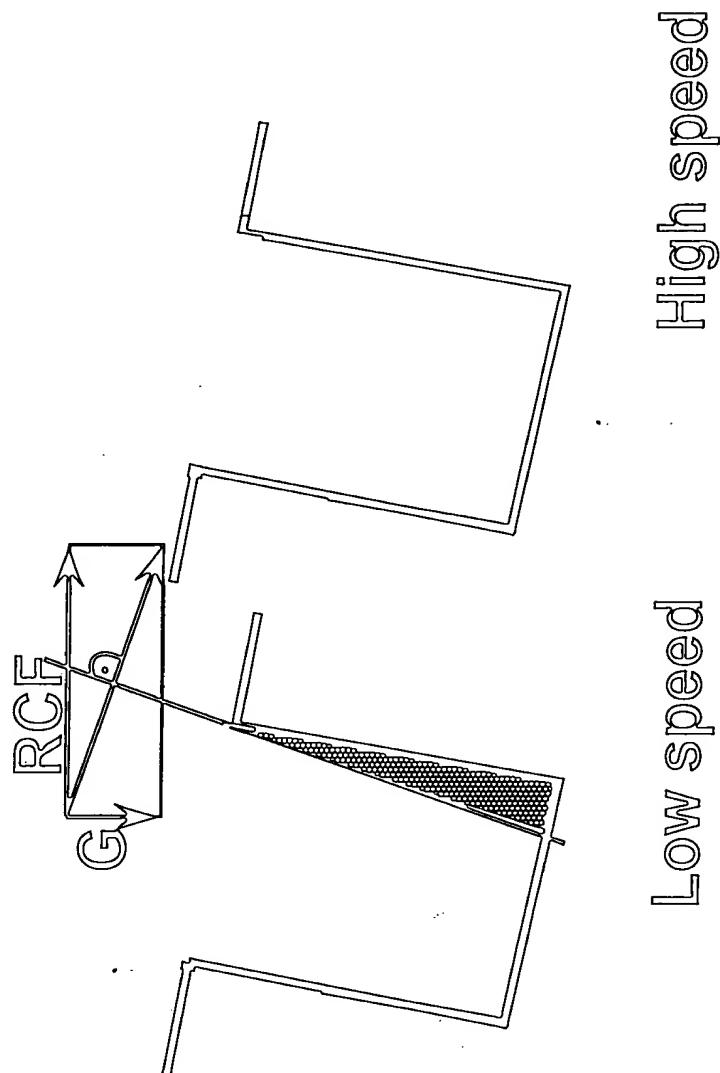


Fig. 4C

Fig. 4B

Fig. 4A